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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/764,875	01/17/2001	Craig A. Rosen	PJZ02	6696

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EXAMINER	
SWITZER, JULIET CAROLINE	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No.	Applicant(s)	
	09/764,875	ROSEN ET AL.	
	Examin r	Art Unit	
	Juliet C. Switzer	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-24 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 14, 15, and 21, drawn to nucleic acids, vectors, host cells, classified in class 536, subclass 23.1, for example.

II. Claims 11-12 and 16, drawn to a polypeptide, classified in class 530, subclass 350, for example.

III. Claim 13, drawn to an antibody, classified in class 530, subclass 387.1.

IV. Claim 17, drawn to a method of treatment using a polynucleotide, classified in class 514, subclass 44.

V. Claim 18, drawn to method of diagnosis of mutation in DNA, classified in class 435, subclass 6.

VI. Claim 19, drawn to method if diagnosis via measuring polypeptide expression, classified in class 435, subclass 7.1

VII. Claim 20, drawn to method of identifying a binding partner, classified in class 435, subclass 7.1.

VIII. Claim 22, drawn to a method for identifying polypeptide activity in an assay, classified in class 436, subclass 501.

IX. Claim 23, drawn to a binding partner, classified in class 530, subclass 300, for example.

X. Claim 24, drawn to method of treatment using a polypeptide, classified in class 424, subclass 130.1, for example.

The inventions are distinct, each from the other because of the following reasons:

2. The inventions of Groups I, II, and III are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of Group I is composed of nucleotides linked in phospodiester bonds and arranged in space as a double helix. The polypeptide of Group II is composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops (transmembrane domain). The antibody of Group III is also composed of amino acids linked in peptide bonds and arranged spatially in a very specific tertiary structure that allows that antibody to specifically bind to particular regions, i.e. epitopes, of the encoded polypeptide. Further, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associated via disulfide bonds into a Y-shaped symmetric dimer. Furthermore, the products of Groups I, II and III can be used in materially different processes, for example, the DNA of Group I can be used in hybridization assays, the antibody of Group III can be used in immunoassay, the polypeptide of Group II can be used to make fusion protein with an enzymatic function. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of Groups I, II, and III are patentably distinct from each other.

3. Inventions I and IV, inventions I and V and inventions I and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another

materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of invention I can be used in a wide variety of methods, as is exemplified by the instant claim set. The products can be used in treatment, detection and expression methods, for example.

4. Inventions I is unrelated to inventions VI, VII, IX and X. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of inventions VI, VII, and X do not set forth or require the nucleic acids and related products of invention I. The products of invention IX are unrelated in structure and function to the nucleic acids of invention I.

5. Inventions II and IV, inventions II and V and inventions II and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of inventions IV and V do not set forth or require the polypeptides of invention II. The products of invention IX are unrelated in structure and function to the polypeptides of invention II.

6. Invention II is related to inventions VI, VII, VIII and X as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of invention II can be used in a

wide variety of methods, as exemplified by the claims. Such methods include, treatment, screening in binding assays, and diagnosis of disease.

7. Invention III is unrelated to inventions IV, V, VI, VII, VIII, IX and X. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of inventions IV, V, VI, VII, VIII, and X do not set forth or require the antibodies of invention III. The products of invention IX are unrelated in structure and function to the antibodies of invention III.

8. Inventions IV, V, VI, VII, VIII, and X are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case all of the groups are drawn to separate methods which have different effects and utilize different reagents and method steps, thus having different modes of operation.

9. Inventions VII and IX are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the binding partners of invention IX are undefined in structure, but could, for example, encompass a polypeptide which could also be made by a synthetic process or by expression of a nucleic acid.

10. Invention IX is unrelated to the methods of inventions IV, V, VI, VII, and X. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they

have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which do not recite or utilize the binding partners of invention IX.

11. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-X, and each particular sequence require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Further Restriction Applicable to All Groups

Each group detailed above reads on hundreds patentably distinct groups, wherein each of the distinct groups is drawn to a particular nucleic acid sequence or polypeptide sequence, or products (antibodies and binding partners) defined by interaction with particular nucleic acid or polypeptide sequences, or methods which depend from these. Applicants must further elect primers to a single sequence (polypeptide or polynucleotide) for examination with whichever claim set is elected. For whichever primer set is elected, applicant should identify which specific SEQ ID NO's as are related to the elected claims.

Prior to allowance, non-elected subject matter will be required to be deleted from any allowable claims.

Applicant is advised that examination will be restricted to only the elected SEQ ID NO. and should not to be construed as a species election.

With regard to the restriction between individual sequences, each sequence is patentably distinct because they are unrelated sequences, i.e. these sequences are unrelated because they do

not share a common structure. A reference against one would not anticipate or obviate another, and thus for each particular sequence a separate search of the patent and non-patent literature is required. These separate searches would impose undue burden on the examiner.

12. A telephone call was made to Mark Hyman on 9/26/03 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is 703 306 5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on 703 308 1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305 3592 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0196.

Juliet C. Switzer
Patent Examiner
Art Unit 1634

September 28, 2003